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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,366

02/02/2005

Michele Orlando

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

08/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/506,366	Applicant(s) ORLANDO ET AL.	
	Examiner EVERETT WHITE	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,39,42-47 and 56-78 is/are pending in the application.
- 4a) Of the above claim(s) 57-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,39,42-47,56 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/03/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed May 3, 2010 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 1-36, 38, 40, 41 and 48-55 have been canceled;
- (B) Claims 37, 39, 56 and 74 have been amended;
- (C) Comments regarding Office Action have been provided drawn to:
 - (I) 112, 2nd paragraph rejection, which has been withdrawn in view of the amendment to the claims;
 - (II) 102(b) rejection, which has been withdrawn in view of the amendment to the claims;
 - (III) 103(a) rejection, which has been withdrawn in view of the amendment to the claims.

2. Claims 37, 39, 42-47, 56-78 are pending in the case. Claims 57-73 are withdrawn from consideration as been drawn to non-elected inventions.

Foreign Priority Claimed

3. This application is a 371 of PCT/EP03/02084 International Filing Date: February 28, 2003 published in German, which claims foreign priority to Germany 10209822.0 under 35 U.S.C. 119(a)-(d). It is noted that PCT/EP03/02084 and Germany 10209822.0 (March 6, 2002) are in German, no translation of the documents into English has been provided.

Information Disclosure Statement

4. The information disclosure statement filed May 3, 2010 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

New Ground of Rejection

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 37, 39, 42-47, 56 and 74-78 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-19 of U.S. Patent No. 7,258,661 ('661) in view of Domb et al (U.S. Patent No. 6,011,008).

The '661 patent discloses a starch/active-substance conjugate comprising the formula (II) recited in Claim 10 of the '661 patent wherein R” denotes a straight-chained or branched alkyl, aryl, or aralkyl group; R-CO- denotes an oxidized substituted or unsubstituted starch radical, which is oxidized at the reducing end group to form a carboxylic acid; and R' is the radical of an active substance, which embraces the conjugate of hydroxyalkylstarch and a low molecular weight substance of the instant claims since the conjugate of the instant claims involve coupling the terminal aldehyde

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group of the starch molecule with a functional group on the low molecular substance to form a covalent bond. The active substance of the starch/active-substance conjugate of the '661 patent can be selected from a peptide, a protein, an antibiotic, a nucleic acid , or a hormone.

The instantly claimed conjugate of hydroxyalkylstarch and a low molecular weight substance differs from the starch/active-substance conjugate of the '661 patent by claiming specific low molecular weight substances.

The Domb et al patent discloses a conjugate of a polysaccharide and substance that may be selected from a group consisting of amine containing low molecular weight drug and drug derivatives, and low molecular weight polypeptides and polypeptide analogs. The substance of the Domb et al patent includes flucytosine, trimethoprim, mitomycins, doxorubicin, vasopressin and oxytocin which are disclosed in Claims 3 and 6 of the Domb et al patent as well as in Claim 37 of the instant application.

One of ordinary skill in this art would be motivated to combine the teaching of the '661 patent with the teaching of the Domb et al patent since both references disclose polysaccharide having an aldehyde group that can conjugated to a functional group of a peptide, protein or hormone of a low molecular weight substance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the active-substance used in the starch/active-substance conjugate of the '661 patent with one of the low molecular weight substances listed in the Domb et al patent in view of the recognition in the art, as evidenced by Domb et al patent that such conjugates provides water-soluble oxidation sensitive substances with are suitable for parenteral administration.

7. Applicant's arguments with respect to claims 37, 39, 42-47, 56 and 74-78 have been considered but are moot in view of the new ground(s) of rejection.

8. Claims 37, 39, 42-47, 56 and 74-78 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-8 and 10 of U.S. Patent No. 7,541,328 ('328) in view of Domb et al (U.S. Patent No. 6,011,008).

The '328 patent discloses a hydroxyethylstarch-protein conjugate characterized in that the binding interaction between the hydroxyethylstarch molecule and the protein is a single covalent bonding which is the result of a coupling reaction between (i) the terminal aldehyde group of the hydroxyethylstarch molecule and (ii) a primary amino group of the protein to form a Schiff's base, which embraces the conjugate of hydroxyalkylstarch and a low molecular weight substance of the instant claims since the hydroxyalkylstarch of the instant claims may be selected as hydroxyethylstarch (see instant Claim 47), since the low molecular weight substance obviously include proteins as demonstrated by the compounds recited in instant Claim 37, and since the coupling reaction between the aldehyde group of the hydroxyethylstarch molecule and the amino group of the protein can form a Schiff's base.

The instantly claimed conjugate of hydroxyalkylstarch and a low molecular weight substance differs from the starch/active-substance conjugate of the '328 patent by claiming specific low molecular weight substances.

The Domb et al patent discloses a conjugate of a polysaccharide and substance that may be selected from a group consisting of amine containing low molecular weight drug and drug derivatives, and low molecular weight polypeptides and polypeptide analogs. The substance of the Domb et al patent includes flucytosine, trimethoprim, mitomycins, doxorubicin, vasopressin and oxytocin which are disclosed in Claims 3 and 6 of the Domb et al patent as well as in Claim 37 of the instant application.

One of ordinary skill in this art would be motivated to combine the teaching of the '328 patent with the teaching of the Domb et al patent since both references disclose polysaccharide having an aldehyde group that can be conjugated to a functional group of a protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the active-substance used in the starch/active-substance conjugate of the '328 patent with one of the substances listed in the Domb et al patent in view of the recognition in the art, as evidenced by Domb et al patent that such conjugates provides water-soluble oxidation sensitive substances with are suitable for parenteral administration.

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9. Applicant's arguments with respect to claims 37, 39, 42-47, 56 and 74-78 have been considered but are moot in view of the new ground(s) of rejection.

Summary

10. Claims 37, 39, 42-47, 56 and 74-78 are rejected; Claims 57-73 are withdrawn from consideration as being directed to non-elected inventions.

Examiner's Telephone Number, Fax Number, and Other Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/

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Supervisory Patent Examiner, Art Unit 1623